K130806

neurovision MEDICAL

JUL 12 2013

510K Summary

Date: 5/1/2013

In accordance with Title 21 of the Code of Federal Regulations, Part 807 and in particular 21 CFR §807.92, the following summary of information is provided:

Applicant Information

Christine Vergely
Regulatory Affairs Manager
Neurovision Medical Products, Inc.
2225 Sperry Ave., Suite 1000
Ventura, CA 93003
PH 805-866-6999
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Device Identification:

Trade or Proprietary Name:	Neurovision Ink Printed Endotracheal Tube Electrode.
Common or Usual Name:	Endotracheal Tube with Electromyography (EMG) monitoring Electrodes.
Device Class:	Class II
Product Code:	ETN

Predicate Device

The subject Neurovision Ink Printed Endotracheal Tube Electrode is substantially equivalent to the following predicate devices concurrently distributed commercially in the U.S.:

- K110989 Neurovision Ink Printed Endotracheal Tube Electrode

Device Description

The Neurovision Ink Printed Endotracheal Tube Electrode is an endotracheal tube with integrated electrodes for electromyographic (EMG) monitoring during surgery. The ET tube is made of a flexible PVC material with an inflatable low pressure cuff. The Neurovision Ink Printed Endotracheal Tube Electrode is provided as a sterile, single use disposable accessory that connects to a compatible EMG monitor to provide an open airway for patient ventilation during EMG neuromonitoring of the Recurrent Laryngel Nerve (RLN).

Intended Use

The Neurovision Ink Printed Endotracheal Tube Electrode is intended for use during surgery and parasurgical care only, with any compatible monitoring system, for continuous EMG monitoring and status assessment of the nerves supplying the laryngeal musculature as well as providing an open airway for patient ventilation.

Technological Characteristics of Device in Relation to Predicate Devices

The Neurovision Ink Printed Endotracheal Tube Electrode is substantially equivalent to the predicated device in intended use and technological characteristics including design,

material composition, function, packaging, and sterilization.

Comparison with the Predicate Device

	Predicate Device	Subject Device
Device Name	Neurovision Ink Printed Endotracheal Tube Electrode	No Change
Indicated Use	The Neurovision Ink Printed Endotracheal Tube Electrode is intended for use during surgery and parasurgical care only, with any compatible monitoring system, for continuous EMG monitoring and status assessment of the nerves supplying the laryngeal musculature as well as providing an open airway for patient ventilation.	No Change
Operating Principle	Receives EMG signal	No Change
Shelf Life	3 years	No Change
Laryngeal Surface Electrode	YES	No Change
Endotracheal Location	YES	No Change
Number of Electrodes	2 or 4	No Change
Electrode Surface Material	Conductive Silver Ink	No Change
Tube & Cuff Materials	PVC	No Change
Reinforcing Material	Dielectric coating	**Dielectric coating attached to tube by non-phthalate PVC adhesive.**
Tube Dimensions	Various Dimensions	No Change
Sterilization and Packaging	Sterile, Single Use Only	No Change
Labeling, Instructions for Use, Intended Use	See attachments 1 and 2	No Change

Nonclinical testing, including valve functionality, electrode impedance and bend tests demonstrated that the subject Neurovision Ink Printed Endotracheal Tube Electrode is substantially equivalent to the predicate.
Biocompatibility testing included ISO 10993-11 Systemic Toxicity, ISO 10993-10 Intracutaneous Sensitivity and ISO 10993-10 Irritation and Skin Sensitization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 12, 2013

Neurovision Medical Product, Inc.
Ms. Christine Vergely
Regulatory Affairs Manager
2225 Sperry Avenue, Suite 1000
Ventura, CA 93003

Re: K130806
Trade/Device Name: Neurovision Ink Printed Endotracheal Tube Electrode
Regulation Number: 21 CFR 874.1820
Regulation Name: Neurosurgical Nerve Locator
Regulatory Class: Class II
Product Code: PDQ, ETN, BTR, GWF
Dated: June 12, 2013
Received: June 13, 2013

Dear Ms. Vergely:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130806

Device Name: Neurovision Ink Printed Endotracheal Tube Electrode

Indications For Use:

The Neurovision Ink Printed Endotracheal Tube Electrode is intended for use during surgery and parasurgical care only, with any compatible monitoring system, for continuous EMG monitoring and status assessment of the nerves supplying the laryngeal musculature as well as for providing an open airway for patient ventilation.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Victor Krauthamer -S
2013.07.12 16:49:43 -04'00'

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number _____